UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, DC 20460

August 25, 2000

OFFICE OF
ENVIRONMENTAL INFORMATION

MEMORANDUM

SUBJECT: External Review Draft of *Overview of the EPA Quality System*

FROM: Nancy W. Wentworth /s/
Director, Quality Staff (2811R)

TO: Peer Review Panel

Attached for your review is the peer review draft of the *Overview of the EPA Quality System*, dated September 2000. This document identifies the quality management requirements for developing and implementing a quality systems that supports the Environmental Protection Agency's Quality System. It is intended to provide a brief summary of the EPA Quality System for those who are not familiar with the system but are subject to its requirements.

Comments, suggestions, and editorial changes are solicited for all sections. Additionally, I ask that you carefully review the document with consideration to the following questions:

1. Can this document be used to quickly identify specific organizational requirements, specific requirements for individuals, and the related documentation?

2. Is the document too long? If so, what sections can be shortened?

3. Is the intended use of this document stated clearly in the text? This document is not intended to provide details on the requirements, but only to identify the requirements and show where to go for more information. For example, this document is not intended to show the who, what, where, when, and why of Quality Management Plans but only to help individuals identify if they need a QMP, and if so, where to go for more information.

4. Is the purpose and importance of having a quality system clear? If not, what additional information should be included?

5. Does Figure 1 enhance your understanding of the Quality System?

6. For non-EPA personnel, can you find the requirements that apply to you and identify where to get more information? Is there anything missing that you would like to see?

7. For EPA QA personnel who are extremely familiar with the Quality System, please consider the following questions:

   a. Can you use this document to educate individuals who are unfamiliar with the Quality System? If not, how can this document be changed?
   b. Do you see your program within this document? If not, what elements of your program are missing?
   c. Can you recommend other useful references to include in Appendix A?
   d. Are there any specific areas which you feel may limit the flexibility within your individual program? (This is not the intention of this document.)

8. For EPA personnel with new QA management responsibilities, please consider the following questions:

   a. Can you easily identify what requirements you need to address?
   b. Does it provide enough background information?
   c. Would this document have been useful for you when you were first assigned quality management responsibilities? If not, what information is missing?

Please submit your comments by November 30, 2000, to:

Overview Comments
Attn: Brenda Odom
Quality Staff (2811R)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460

In addition, comments may be faxed to (202) 565-2441 or e-mailed to quality@epa.gov.

Your input is very important and I appreciate your time spent in reviewing this document. I believe this document will help educate individuals, both EPA and otherwise, about the importance of an effective Quality System and the specific EPA requirements.

Attachment

United States
Environmental Protection
Agency

Office of Information
Quality Staff
Washington, DC 20460

September 2000

Overview of the EPA Quality System

Peer Review Draft

September 2000

Quality Staff
Office of Environmental Information
United States Environmental Protection Agency

Washington, DC 20460

FOREWORD

This document identifies the quality management requirements for organizations and individuals that must develop and implement a quality systems that supports the Environmental Protection Agency. This document is one of the *EPA Quality System Series* documents which describe EPA policies and procedures for planning, implementing, and assessing the effectiveness of a quality system. Questions regarding this or other *EPA Quality System Series* documents should be directed to:

U.S. EPA
Quality Staff (2811R)
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Phone: (202) 564-6830
Fax: (202) 565-2441
e-mail: quality@epa.gov

Copies of *EPA Quality System Series* documents may be obtained from the Quality Staff or by downloading them from the Quality Staff Home Page:

www.epa.gov/quality

As required by EPA Order 5360 A1 (May 2000), this document is valid for a period of up to five years from the official date of publication. After five years, this document shall either be reissued without change, revised, or withdrawn from the Quality System Series documentation.

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OVERVIEW OF THE EPA QUALITY SYSTEM

1. BACKGROUND

A quality system is the means by which an organization manages the quality aspects of its operations in a systematic, organized manner the same as an organization manages its financial operations or health and safety programs. It encompasses a variety of technical and administrative elements, including:

- policies and objectives,
- organizational authority,
- responsibilities,
- accountability, and
- procedures and practices.

A quality system provides the framework for planning, implementing, and assessing work performed by an organization and for carrying out quality assurance (QA) and quality control (QC) activities (see Box 1).

Box 1. Quality Control vs. Quality Assurance

Quality control (QC) is an overall system of technical activities that measures the performance of a process, item, or service against defined standards to verify that the performance meets the stated requirements.[a] QC is typically applied by technical personnel. Example QC activities include the use of control samples during sample collection, handling, and analysis, and activities such as data review and data validation.

Quality assurance (QA) is an integrated system of management activities involving planning, implementation, assessment, reporting, and improvement to ensure that a process, item, or service is of the type and quality needed.[a] QA is typically applied by managers or technical personnel assigned to a specific oversight role. Example QA activities include technical and management assessments of field and analytical operations.

[a]From ANSI/ASQC E4-1994

This document identifies the requirements for organizations and individuals that must develop and implement Quality Systems that support the EPA Quality System. It describes the components that must be considered as part of a quality system, and the tools for addressing these components. This document is intended to be a reference guide for EPA managers and staff who implement the EPA Quality System.

2. EPA'S QUALITY SYSTEM

The EPA Quality System encompasses both management and technical activities pertaining to the planning, implementation, and assessment of environmental programs within the Agency's mission and scope. The goal of the Agency-wide Quality System is to ensure that environmental programs and decisions are supported by data of the type and quality needed and expected for their intended use, and that decisions involving environmental technology are supported by appropriate quality-assured engineering standards and practices.

3. BENEFITS OF THE EPA QUALITY SYSTEM

Effective implementation of the EPA Quality System leads to several benefits, including:

- *Scientific Data Integrity* – EPA will produce data of known and documented quality.

- *Reduced or Justifiable Resource Expenditures* – Resource expenditures can be reduced as EPA's information needs are more closely matched to the information collection activities. For example, through systematic planning, only the appropriate type, amount, and quality of data will be collected by EPA, others collecting data on behalf of EPA, and others collecting data to satisfy EPA requirements.

- *Effective Management of Internal and External Activities* – The quality system provides documentation of activities and oversight for evaluation purposes. This reduces the potential for waste, fraud, and abuse.

- *Reliable and Defensible Decisions* – When the quality of data is known, it is possible to determine if the data can be used for a specific decision. This reduces the likelihood of challenges to regulations, enforcement actions, permit appeals, etc., resulting from the use of data of uncertain quality.

- *Burden Reduction* – As EPA better defines the data needed for a specific application, the burden on other organizations who are required to collect and/or report these data to EPA may be reduced.

Overall, successful implementation of the EPA Quality System will reduce the Agency's vulnerabilities in decision making and increase EPA's credibility by providing the ability to make reliable, cost-effective, and defensible decisions.

4. STRUCTURE OF THE EPA QUALITY SYSTEM

4.1 Scope

The EPA Quality System applies to environmental programs that encompass:

- the collection, evaluation, and use of environmental data, and

- the design, construction, and operation of environmental technology.

Box 2 contains definitions that are useful in understanding the scope of this system. The EPA Quality System applies uniformly to EPA organizations and to non-EPA organizations funded by EPA. Section 4.3 describes the organizations that are included within the EPA Quality System.

Box 2. Important Definitions[a]

Environmental Programs - activities involving the environment, including but not limited to: characterization of environmental processes and conditions; environmental monitoring; environmental research and development; laboratory operations on environmental samples; and the design, construction, and operation of environmental technologies.

Environmental Data - any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, Environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.

Environmental Technology - an all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from or prevent them from entering the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term will apply to hardware-based systems; however, it will also apply to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

[a]From ANSI/ASQC E4-1994

4.2 Basis

The EPA Quality System is based on ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*. ANSI/ASQC E4 is an American National Standard for quality management practices for environmental programs involving the collection and evaluation of environmental data and the design, construction, and operation of environmental technologies. This standard provides a basis for planning, implementing, documenting, and assessing an effective quality system. EPA requires conformance to this standard through internal Orders and the Code of Federal Regulations (see Section 4.4). Copies of the ANSI/ASQC E4 may be purchased from:

ASQ Quality Press
P.O. Box 3005
Milwaukee, WI 53201-3005
Phone: (800) 248-1946
www.asq.org

4.3 Organizational Structure of the EPA Quality System

The EPA Quality System is composed of individual quality systems developed and implemented by the various EPA Regions, National Program Offices, and the National Centers and Laboratories in the Office of Research and Development. Overall, there are more than 40 EPA organizations that maintain quality systems. These organizations are usually at the Regional Office level, the level immediately below each National Program Office, and at the National Center and Laboratory level (see Figure 1[1]). Specialized, highly-visible programs (for example, EPA's Great Lakes National Program) also may have their own quality systems. Typically, such programs cut across organizational lines and have their own organizational infrastructure. Non-EPA organizations that receive funding from EPA to perform environmental programs must then have a quality system to support that work.

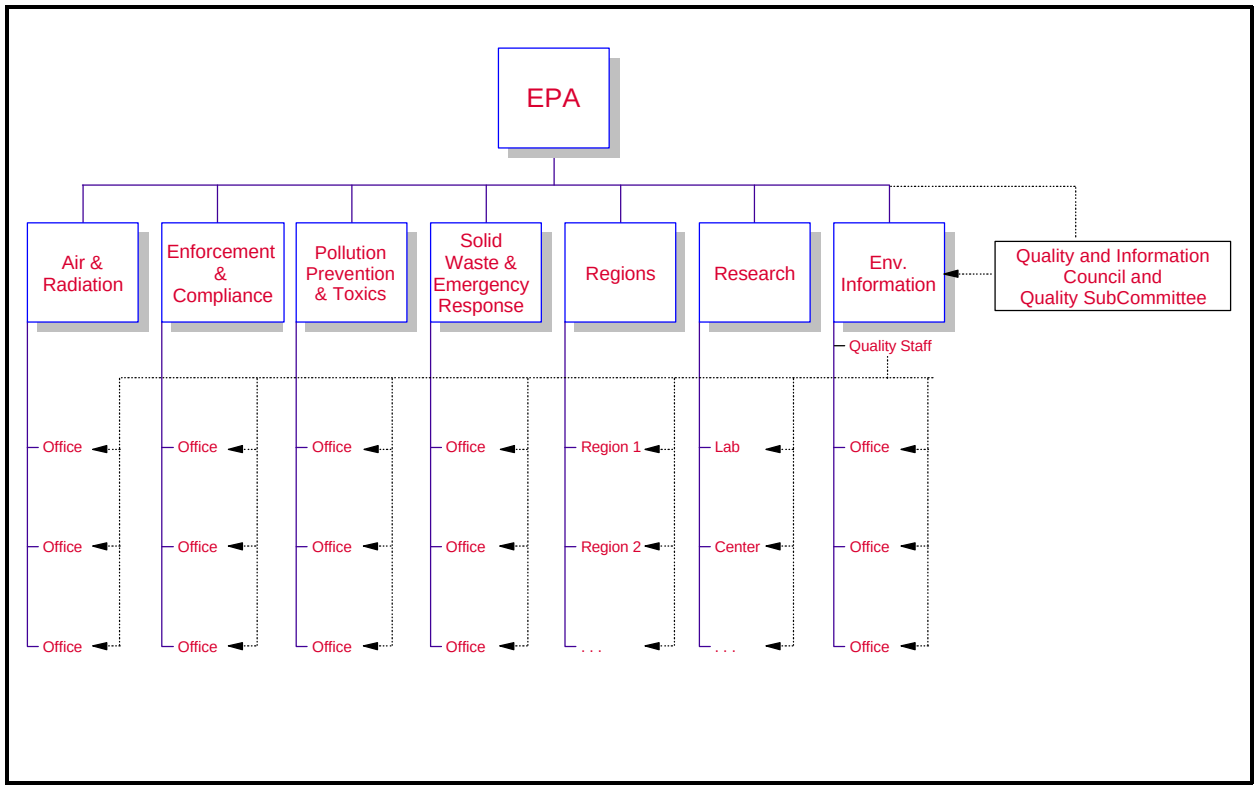

Figure 1. Example EPA Organizations and Quality Assurance

[1]Note, not all EPA Offices are shown on Figure 1. At the date of publication of this document, EPA Program Offices included the Great Lakes National Program Office, Office of Air and Radiation, Office of Administration and Resource Management, Office of the Chief Financial Officer, Office of Enforcement and Compliance, Office of Environmental Information, Office of the Inspector General, Office of Pollution Prevention and Toxic Substances, Office of Research and Development, and the Office of Solid Waste and Emergency Response.

Because of the diversity of different programs within EPA, the Agency-wide Quality System is decentralized so organizations can develop individual quality systems. By developing individual Quality Systems, organizations ensure that their quality systems specifically address their needs and objectives. However, each individual quality system must comply with Agency-wide quality system requirements.

4.4 Structural Components of the EPA Quality System

Figure 2 illustrates the components to consider when developing an individualized Quality System. These components are established at the policy, organization/program, and project levels. The functions within each of these levels is as follows:

Policy – this level addresses Agency-wide quality policies and regulations that both EPA organizations and non-EPA organizations must address;

Organization/Program – this level addresses the management and implementation component of the individual Quality System; and

Project – this level addresses the project-specific components that are applied to individual projects to ensure that the needs of the organization are met.

Figure 2 also shows some of the quality management tools EPA has developed to assist in the implementation of the quality system requirements. These tools are italicized in the discussion below and described in Appendix A.

The use of quality management components and tools in the Organization/Program and the Project levels is based on a graded approach where components and tools are applied according to the scope of the program and/or the intended use of the outputs from a process. This approach recognizes that a "one size fits all" approach to quality requirements is not appropriate for an organization as diverse as EPA. For example, the quality expectations of a fundamental research program are different from that of a regulatory compliance program because the purpose or intended use of the data differs. Applying a graded approach means that quality systems tools and components for different organizations and programs will vary according to the specific objectives and needs of the organization.

4.4.1 Policy Level

The policy level of the EPA Quality System consists of:

✓ Agency-wide policies specific to EPA organizations,

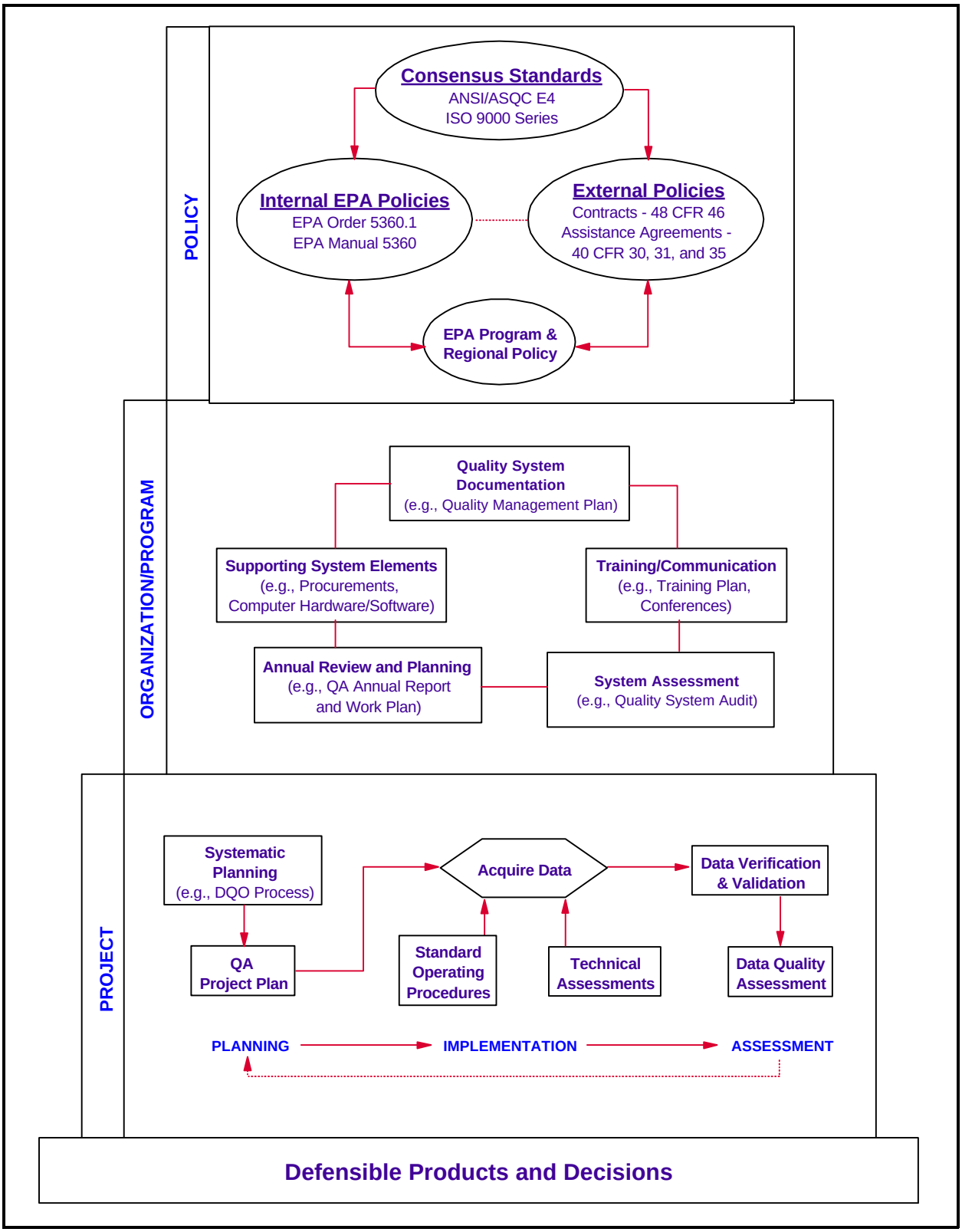

Figure 2. EPA Quality System Components and Tools

- ✓ Agency-wide policies for non-EPA organizations that perform environmental programs on behalf of EPA, and

- ✓ program-specific policies for both EPA and non-EPA organizations. These policies are consistent with one another and are based on the national consensus standard ANSI/ASQC E4.

4.4.1.1 Agency-wide Internal Policy

Agency-wide policies for EPA organizations are contained in two documents:

EPA Order 5360.1 A2 (May 2000), *Policy and Program Requirements for the Mandatory Agency-wide Quality System* – EPA Order 5360.1 establishes the minimum requirements for EPA organizations covered by the mandatory Agency-wide Quality System. All EPA organizations covered by Order 5360.1 are required to develop, implement, and maintain a quality system that demonstrates conformance to the minimum specifications of ANSI/ASQC E4-1994. In addition, this Order contains requirements specific to EPA such as developing Quality Management Plans, ensuring adequate resources, providing training, etc., and also describes responsibilities for EPA management, staff, and Quality Management personnel. Specific requirements for EPA organizations are described in Section 6.

EPA Order 5360 A1 (May 2000), *EPA Quality Manual for Environmental Programs* – EPA Order 5360, the Quality Manual, provides implementation requirements for EPA organizations covered by the mandatory Quality System defined in EPA Order 5360.1. The Quality Manual addresses the implementation of quality management activities, including limitations on the use of non-EPA organizations; reporting requirements; requirements for organizations funded by EPA; requirements for reporting results from applicable environmental programs; Quality System requirements and guidance documents; user-specific QA and QC guidance; and dispute resolution. In addition, the Manual provides details on documentation for demonstrating compliance with Order 5360.1.

Together, these two documents define the Agency-wide Quality System and the requirements EPA organizations must satisfy.

4.4.1.2 Agency-wide External Policy

Quality System policies and requirements for non-EPA organizations funded by EPA are contained in the Code of Federal Regulations (CFR). There are four basic regulations that apply to contracts, grants, and cooperative agreements, as well as any work assignments, delivery orders, or tasks orders which are contained in the above. Box 3 contains information on which requirement applies to an individual or organization. Each regulation is described below:

Box 3. Quality-Related Regulations by non-EPA Organization

	Contract	Cooperative Agreement	Grant*	Inter-Agency Agreement	Agency Mandates
Contractor	48 CFR 1546 48 CFR 46	N/A	N/A	N/A	N/A
Federal Agency	N/A	N/A	N/A	Negotiated into each agreement	Contained in specific Federal Regulation that requires data
Hospital	48 CFR 1546 48 CFR 46	40 CFR 30	40 CFR 30	N/A	Contained in specific Federal Regulation that requires data
Institute of Higher Education	48 CFR 1546 48 CFR 46	40 CFR 30	40 CFR 30	N/A	Contained in specific Federal Regulation that requires data collection
Local Government	48 CFR 1546 48 CFR 46	40 CFR 31 40 CFR 35	40 CFR 31 40 CFR 35	N/A	Contained in specific Federal Regulation that requires data
Non-profit Organization	48 CFR 1546 48 CFR 46	40 CFR 30	40 CFR 30	N/A	Contained in specific Federal Regulation that requires data
Regulated Entity	N/A	N/A	N/A	N/A	Contained in specific Federal Regulation that requires data collection
State Government	48 CFR 1546 48 CFR 46	40 CFR 31 40 CFR 35	40 CFR 31 40 CFR 35	N/A	Contained in specific Federal Regulation that requires data
Tribal Government	48 CFR 1546 48 CFR 46	40 CFR 31 40 CFR 35	40 CFR 31 40 CFR 35	N/A	Contained in specific Federal Regulation that requires data

*Grants include Performance Partnership Grants and Performance Partnership Agreements.

48 CFR 46, *"Higher-level Contract Requirements"* – Contains requirements for contracts, work assignments, delivery orders, and task orders. Allows Federal agencies to select a national consensus standard as a basis for their quality requirements. EPA will use ANSI/ASQC E4 as the basis for its quality requirements and require that applicants/contractors submit a Quality Management Plan (or equivalent) and/or a QA Project Plan (or equivalent) to demonstrate conformance to the standard.

40 CFR 30, *"Grants and Agreements with Institutions of Higher Education, Hospitals and Other Non-Profit Organizations"* – Contains requirements for organizations identified in title. Requires that grantees comply with the American National Standard, ANSI/ASQC E4. EPA requires that grantees submit a Quality Management Plan and/or a QA Project Plan to demonstrate conformance.

40 CFR 31, *"Uniform Administrative Requirements for Grants and Cooperative Agreement to State and Local Governments"* – Contains requirements for grants and cooperative agreements to State, local, and Tribal Governments. Requires that grantees develop and implement QA practices to produce data of adequate quality to meet project objectives. To clarify this requirement, EPA has issued clarifying language, posted at www.epa.gov/ogd/qa.htm, which is consistent with 40 CFR Part 30. The clarifying language states that grantees must have a quality system that conforms to the American National Standard, ANSI/ASQC E4-1994, and are required to submit a Quality Management Plan and/or a QA Project Plan.

40 CFR 35, "State and Local Assistance" – Contains requirements for financial assistance agreements to State and local governments. Requires that grantees comply with 40 CFR 31.

Quality requirements are negotiated into interagency agreements and consent agreements, and may be included in consent orders. This is done on a case-by-case basis by the EPA organization sponsoring or overseeing the work. Additional quality requirements may be included in Federal regulations. For example, 40 CFR 160.35, "Federal Insecticide, Fungicide, Rodenticide Act," contains additional quality management requirements specific to this Act.

4.4.1.3 Program Specific Policies

Each EPA organization integrates the Agency-wide quality policies into its specific individual quality policies, procedures, and practices. EPA organizations may also tailor internal policies to their individual needs which is described in the organization's Quality Management Plan (see Appendix A, Section A.1.1). In addition, EPA organizations may have additional requirements for non-EPA organizations to ensure that program-specific goals and objectives are satisfied.

4.4.2 Organization/Program Level

The organization/program level includes components that affect management policies and processes that have broad application across an organization or program. There are four key components: Quality System Documentation; Management Assessments; Annual Reviews and Planning; and Training. Successful implementation of each component is essential to an effective Quality System.

For each component at the Organization/Program level, EPA has developed quality management tools to assist in the implementation. These tools are italicized in the discussion below and described in Section A.1 of Appendix A. Because EPA has many different organizations with varying missions, each quality system will vary accordingly.

The implementation or use of each component or tool should reflect the needs of the organization relative to its environmental data operations and Agency policy. The Organization/Program level should address the policies and responsibilities that apply to activities that are common to all projects undertaken by the organization. For example, the requirement for a QA Project Plan along with the process for reviewing and approving those plans should be included at the Organization/Program level since the process would apply to all QA Project Plans. Then each QA Project Plan is developed and implemented at the Project level. The Organization/Program level components include:

Quality System Documentation – Documentation that describes the authorities, policies, and procedures specific to an organization's quality. EPA organizations are required to document their quality system in a *Quality Management Plan (QMP).*

System-level Assessments – Systematic assessments of a program and/or organization's quality system. EPA uses *Quality Systems Audits (QSA)* to assess EPA and supporting organizations. EPA organizations are required to assess their organization at least annually.

Annual Reviews and Planning – A yearly review of the activities within, and changes to, an organization's quality system; work accomplished; and the planning of future projects requiring quality management attention. Each EPA organization is required to submit a *QA Annual Report and Work Plan (QAARWP)* to document their review and planning.

Training - Methods and techniques to ensure that all personnel having responsibility within the quality system for management and data collection activities have the necessary skills, knowledge, and proficiency to complete their tasks in accordance with their quality system's policies and procedures. EPA organizations are required to document their *Training Program* in their Quality Management Plan.

4.4.3 Project Level

The project level applies to projects or programs within an organization that involves environmental data generation, acquisition, and use. There are three components within this level – planning, implementation, and assessment – which correspond to the Project Life Cycle (see Figure 3) and lead to a specific product or decision. Each feed back into the others for refinements and improvement and are critical for ensuring that the quality of environmental information can be determined and for determining whether the information can be used for a specific decision. Complete reporting of the data planned, collected, and analyzed (including the relevant QA and QC data and the results from assessments) enable decision makers to judge the quality of scientific information available to support their decisions.

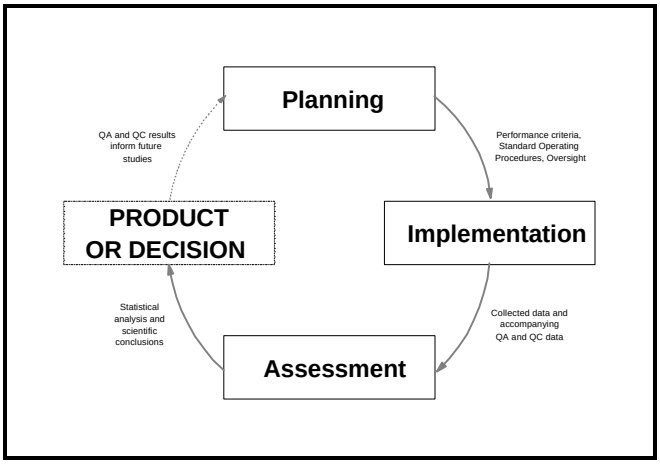

Figure 3. The Project Life Cycle

For each component at the Project level, EPA has developed quality management tools to assist in the implementation. These tools are italicized in the discussion below and described in Section A.2 of Appendix A. The quality system practices for the project level are typically implemented by the individual organization for all activities comprising its mission.

Planning: Prospective data users use a *systematic planning process*, such as the *Data Quality Objectives Process*, to develop performance criteria for the data (i.e., the type, quantity, and quality of data needed to serve their needs), to develop a sampling plan that satisfies the criteria, and to determine the level of oversight and QC activities needed to ensure the criteria are satisfied. The systematic planning results are documented in the *QA Project Plan.*

Implementation: Data are acquired according to the methods and procedures documented in the approved QA Project Plan and any approved *Standard Operating Procedures*. Oversight is performed using *technical audits and assessments* to assess whether or not data are being acquired as stated in the QA Project Plan.

Assessment: Project personnel use technical knowledge and statistical methods to determine whether or not the data meet the user's needs. The data are formally *verified and validated* to ensure that the measured values are free of gross errors due to procedural or technical problems and then are analyzed to determine if they meet the performance criteria documented in the QA Project Plan (*data quality assessment*). Results from the assessment component are then fed back into the planning component.

5. REQUIREMENTS

5.1 Requirements for EPA Organizations

There are 12 basic quality management requirements defined in EPA Order 5360.1 for all EPA organizations covered by the EPA Quality System. These requirements are to:

- ✓ Conform to the minimum specifications of ANSI/ASQC E4-1994;
- ✓ Identify a QA Manager and ensure the organizational independence of this QA Manager function from environmental data operations;
- ✓ Develop a Quality Management Plan and implement this plan following Agency approval;
- ✓ Provide sufficient resources to implement the quality system;
- ✓ Perform assessments of the effectiveness of the quality system at least annually and implement corrective actions based on assessment results in a timely manner;
- ✓ Submit an QA Annual Report and Work Plan (QAARWP) for the organization that summarizes the previous year's activities and outlines the work proposed for the current year;
- ✓ Implement Agency-wide Quality System requirements in all applicable EPA-funded extramural agreements;
- ✓ Provide appropriate training for all levels of management and staff to assure that QA and QC responsibilities and requirements are understood at every stage of project implementation;
- ✓ Use a systematic planning approach to develop acceptance or performance criteria for all work covered by the EPA Quality System;
- ✓ Have approved QA Project Plans, or equivalent documents, for all applicable projects and tasks involving environmental data; and
- ✓ Assess existing data, when used to support Agency decisions or other secondary purposes, to verify that they are of sufficient quantity and adequate quality for their intended use;

Specific tools for satisfying these requirements are defined in Appendix A. EPA Order 5360.1 also contains program-specific requirements that EPA organizations must address in addition to requirements specific to EPA managers and staff.

5.2 Requirements for Non-EPA Organizations

Non-EPA organizations are required to develop quality systems to support their environmental programs funded by EPA. Organizations that may be affected by the EPA Quality System requirements include: other Federal departments and agencies; State, local, and Tribal governments; academic and other non-profit organizations; and commercial business enterprises. Quality management requirements are defined through the Federal Acquisition Regulations which specify exactly what an organization must do to comply with EPA policy, or are negotiated into agreements that are not covered by the Federal Acquisition Regulations (see Section 4.4). In addition, each EPA organization's Quality Management Plan describes how the organization will interact with, and any additional requirements for, the organizations they fund.

In general, EPA requires that recipients of funds for work involving environmental data collection comply with the American National Standard ANSI/ASQC E4-1994, "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs." To demonstrate conformance to this standard, EPA requires two forms of documentation:

1. Documentation of the organization quality system (usually called a Quality Management Plan), and/or

2. Documentation of the application of QA and QC activities to an activity-specific effort (usually called a QA Project Plan).

Use of existing quality system documentation, such as documentation that a company is ISO 9000 certified, may be acceptable alternatives.

For small grants and contracts, these two documents may be combined into a single document that describes the organization's quality system and the application of this system to the work performed under the grant or contract. This can only be done with permission of the EPA QA Manager who will identify which elements should be addressed in this combined document

6. RESPONSIBILITIES

Responsibility for the EPA Quality System is spread across the Agency. However, the EPA organizations described below each have a specific role and set of responsibilities. These responsibilities are summarized in Box 4.

Box 4. Quality Management Responsibilities for EPA Organizations

	Asst. Administrator Env. Information[1]	Quality Staff	National Program Offices	Regional Offices
Quality Management Policies	Issues policies recommended by Quality Staff and/or Quality and Information Council and Quality Subcommittee	Develop for Agency-wide use	Develop for program – may apply to Regions Apply Agency-wide policies	Develop for Region, and State, local, and Tribal governments Apply Agency-wide policies
Quality Management Plan	Approves EPA plans	Review EPA organization's plans Recommend approval to the Sr. Official for Quality	Develop for each program laboratory and organization Review/approve the plans of non-EPA organizations funded by EPA	Develop for Region Review/approve the plans of State, local, and Tribal governments. and non-EPA organizations funded by EPA
Quality Management Procedures and Guidance	Issues procedures and guidance developed by Quality Staff	Develop for Agency and non-EPA organizations funded by EPA	Develop for program and activities delegated to Regions Coordinate implementation with Regions	Develop for Regions – may apply to State, local, and Tribal governments
Resources for Quality Management Activities	Recommend improvements and balance resource allocation	Monitor resource allocation across Agency and highlight differences and inconsistencies	Provide sufficient resources to implement the organization's Quality Management Plan	Provide sufficient resources to implement the organization's Quality Management Plan
Management Assessments	Mandates Agency-wide corrective actions	Review each EPA organization at least once every 3 years Identify Agency-wide problems and corrective actions	Perform internal assessments Assess supporting organizations (EPA or otherwise)	Perform internal assessments Assess supporting organizations (EPA or otherwise), including State Agencies

Box 4. Quality Management Responsibilities for EPA Organizations

	Asst. Administrator Env. Information[1]	Quality Staff	National Program Offices	Regional Offices
QA Annual Report and Work Plan	Report to EPA Administrator	Compile information in report to AA/OEI and EPA Administrator	Report yearly	Report yearly
Communication and Outreach	Represents EPA on quality practices and issues.	Perform outreach and consulting Host monthly conference calls, annual National QA meeting) Represents EPA on quality practices and issues	Liaison with Quality Staff, other EPA QA Managers and assistance agreement holder QA Managers Represent EPA on program-specific quality practices and issues	Liaison with Quality Staff, other EPA QA Managers and State, local, and Tribal governments Represent EPA on Regional quality practices and issues
Training	Issue generic training materials	Develops generic training materials Provides generic training on limited basis	Develop program-specific training Provide training to program management and staff	Develop Region-specific training Provide training to Regional management and staff Ensure training is available for State, local, and Tribal governments
Performance Standards	Issue general standards policy	Develop general standards policy	Ensure QA-related activities reflected in performance standards	Ensure QA-related activities reflected in performance standards

[1]In conjunction with the Quality and Information Council and Quality Subcommittee.

6.1 Agency Senior Management Official for Quality

The Assistant Administrator for Environmental Information is the Agency's Senior Management Official for Quality and is responsible for developing and coordinating the mandatory Agency-wide Quality System and directing its implementation among Program Offices, Laboratories, Regional Offices, contractors, and grantees producing environmental data for EPA. In addition to the Agency-wide Quality responsibilities, the Assistant Administrator for Environmental Information has responsibilities specific to this office which are described in Section 6.4.

6.2 Quality and Information Council/Quality Subcommittee

The Quality and Information Council is an advisory group of Agency senior managers that assists the Assistant Administrator for Environmental Information in developing and implementing the Agency's quality and information goals and policies. This council is supported by the Quality Subcommittee which addresses Agency-wide policy issues in the implementation of the quality program, including consistency of implementation. Both groups function as a forum in which ideas and issues with regards to the Agency-wide Quality System can be raised.

6.3 Office of Environmental Information's Quality Staff

The Quality Staff of the Office of Environmental Information is the Agency organization assigned the responsibility for developing Agency-wide policy and procedures and for overseeing the implementation of the EPA Quality System. Responsibilities for this staff are shown in Box 4.

6.4 National Program Offices

The National Program Offices have the principal responsibilities for implementing the environmental policies, regulations, and programs comprising the Agency's mission. (See Section 4.3 for example EPA Program Offices.) The Assistant or Associate Administrator of each National Program Office is responsible for its quality system. Specific responsibilities of the National Program Offices are described in Box 4. Each National Program Office has a QA Representative that reports to the Assistant Administrator. These representatives are advisors for QA and QC activities and assist in the planning, implementation, documentation, and assessment of the quality systems for organizations within the Program Office. Each line office within a National Program Office typically has a QA Manager, QA Officers, and/or QA Coordinators to provide support to the ongoing operations of the organization.

Some organizations within a National Program Office may have programs that are delegated to the EPA Regions and/or to States and Tribal governments or are supported by Regional, State, or EPA National laboratories. In this case, the Quality Management Plan for the National Program Office's organization documents the quality management responsibilities for these programs.

6.5 EPA Regional Offices

The EPA Regional Offices coordinate implementation of national programs with the State, local, and Tribal governments. In addition, the Regions are the principal interface between EPA and the regulated community and are responsible for the oversight of State, local, and Tribal programs funded by EPA. The Regions also share responsibility for programs that are under the jurisdiction of the EPA Program Offices. Each Regional Administrator is responsible for the quality system in the Region and each Regional Office has a QA Manager, who has the principal quality management oversight responsibility. Specific responsibilities for the EPA Regional Offices are shown in Box 4.

6.6 Individual Responsibilities

Figure 4 shows the general quality management components, tools, and responsibilities of individuals within EPA. Individual responsibilities vary based on the quality system of the organization and the requirements of the organization's Quality Management Plan. In general, the quality management components and tools described in Section 4.4 apply to the same individuals within an organizations. For example, the project-level components generally apply to all EPA project personnel.

6.6.1 EPA Quality Personnel Responsibilities

EPA organizations are required by EPA Order 5360.1 to identify a QA Manager who will report on quality issues to the senior management of the organization; provide independent oversight; and assure the implementation of the organization's quality system. This individual must function independently of direct environmental data generation, model development, or technology development responsibility. See Gee (1996) and Pyzdek (1996) for a discussion on roles and activities of a QA Manager for a general organization.

The Order also defines the responsibilities of the QA Manager and other quality management personnel to include: facilitating the development and maintaining the organization's Quality Management Plan; representing the organization on matters pertaining to quality management; providing expert assistance to project personnel on QA and QC issues; developing and implementing a QA Training Program; reviewing and/or approving quality management documentation; providing quality management support to project personnel; and overseeing and assessing the organization's quality system. In addition to these general responsibilities, each EPA organization's Quality Management Plan defines specific responsibilities for its QA Manager and other quality management personnel.

6.6.2 EPA Managers and Staff

Responsibilities for EPA managers and staff are defined in their organization's Quality Management Plan. However, EPA managers are also responsible for ensuring that adequate

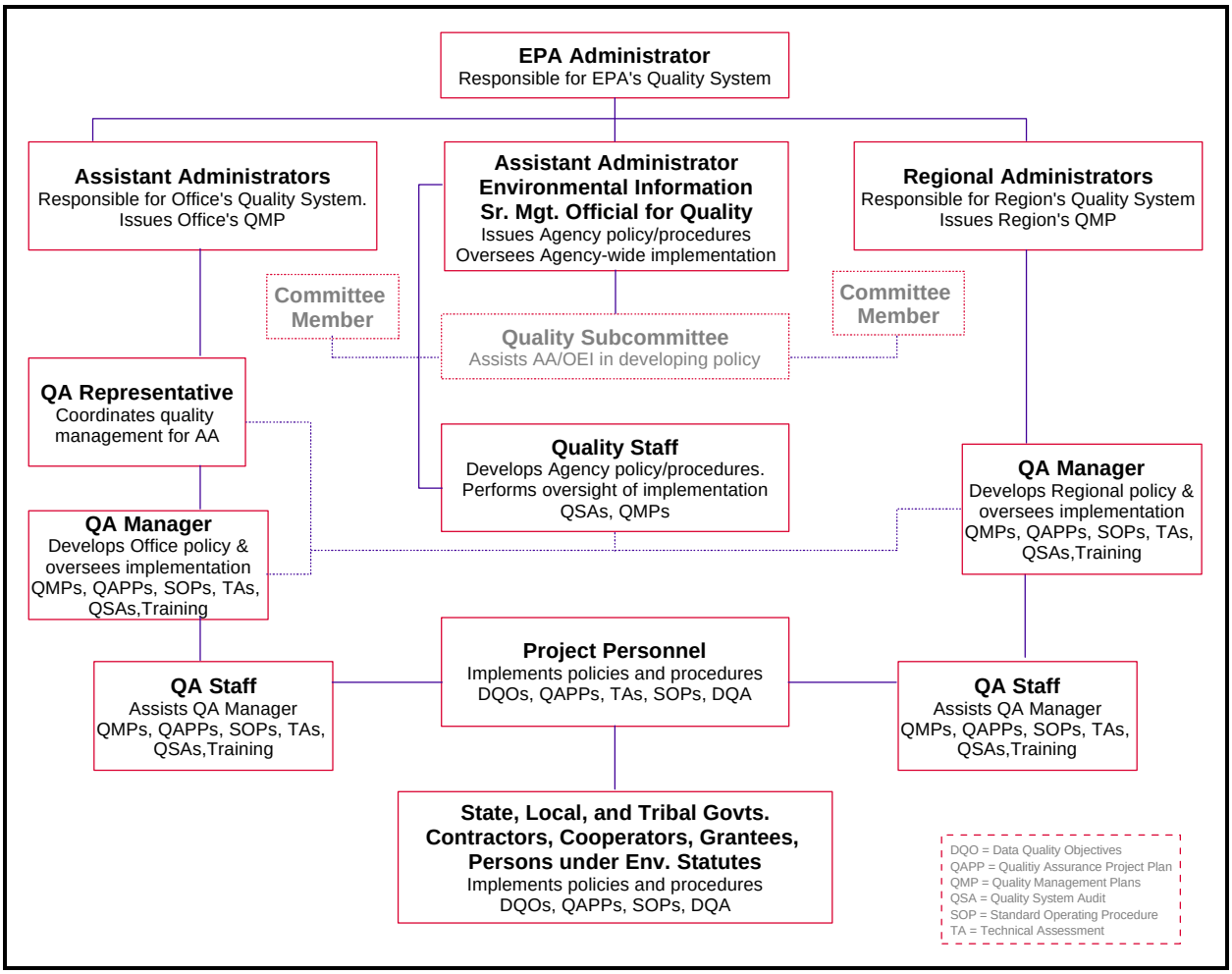

Figure 4. Quality Management Responsibilities by Individual

resources are available for quality management activities needed to accomplish program quality goals; ensuring that all organizational components and all environmental programs under the managers supervision comply with EPA Order 5360.1. In addition, both EPA managers and staff are responsible for ensuring their applicable intramural and extramural programs and activities comply fully with EPA Order 5360.1 and for assuring that the results of environmental programs are of sufficient quantity and adequate quality for their intended use.

6.6.3 EPA Contracting Officers and Contracting Officer's Representatives

Responsibilities for EPA's Contracting Officers and Contracting Officer's Representatives are contained in the EPA Manual 1900 (EPA 1998), *Contracts Management Manual*. Quality-related requirements specific to the EPA Quality System, such as the use of a QA Review Form and criteria for the Technical Evaluation Panel, are contained in Chapter 2 of this Manual.

7. PROGRAM LIAISON ACTIVITIES

EPA uses several approaches to disseminate quality-related information to quality professionals and to collaborate with other organizations on new initiatives to improve quality management practices and procedures. These approaches include conference calls, guidance, conferences, Internet sites, and participation in professional societies.

Conference Calls: The EPA QA Managers participate in monthly conference calls to exchange information and to discuss current issues and activities. The Quality Staff organizes the calls, but the facilitation and agenda planning is done by the individual groups. This process assures that issues of particular interest to the Regions or research laboratories are identified and discussed. These calls are restricted to EPA personnel only. EPA Program Offices may also sponsor a conference call for their quality management personnel.

Quality System Series Documents: EPA publishes a series of documents that describe the EPA policies and procedures for planning, implementing, and assessing the effectiveness of the EPA Quality System and provide criteria and guidance on satisfying EPA quality requirements. These documents are called the Quality System Series.

Annual Quality Management Conference: EPA sponsors an annual conference so that EPA and other quality professionals can share experiences in managing and implementing their quality systems and QA and QC practices. These conferences may be general in scope or have a specific focus, depending on the needs expressed by the quality management community. The conferences include presentations on national issues and feature presentations by EPA and other organizations on technical issues. The Quality Staff generally offers training in conjunction with the conference to provide an optional opportunity for education and professional development in quality concepts and practices.

Annual Training Conference: EPA sponsors an annual training conference to equip QA professionals with the knowledge and skills they need to promote effective management and implementation of environmental quality systems. The conference offers practical educational opportunities and workshops of varying lengths that allow conference attendees to participate in QA-related training events that are specific to their organizational needs. The training curriculum includes classes in basic QA and QC concepts and principles as well as specialized and advanced courses.

Web Sites: EPA uses the World Wide Web to disseminate information in an electronic form. The Agency-wide Quality System site (www.epa.gov/quality) contains information on the EPA Quality System, quality requirements for organizations funded by EPA, training, the Annual Conference, and contact persons for each individual EPA organization. This site contains the final Agency-wide Quality Systems Series Documents along with any documents undergoing external peer review. Most Regional Offices and a

few program offices also maintain web sites with quality-related information. A link to these sites is maintained on the Agency-wide Quality System web site.

Professional Societies and Standards Development: EPA participates in the quality management activities of several professional societies and standards developing organizations including the American Society for Quality, the American Society for Testing and Materials, the American National Standards Institute, and the International Organization for Standardization.

8. REFERENCES

40 CFR 30, Code of Federal Regulations, "Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations."

40 CFR 31, Code of Federal Regulations, "Uniform Administrative Requirements for Grants and Cooperative Agreement to State and Local Governments."

40 CFR 35, Code of Federal Regulations, "State and Local Assistance."

48 CFR 46, Code of Federal Regulations, "Federal Acquisition Regulations."

ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, American National Standard, January 1995.

EPA Order 5360 A1 (May 2000). *EPA Quality Manual for Environmental Programs*, U.S. Environmental Protection Agency, Washington, DC.

EPA Order 5360.1 A2 (May 2000). *Policy and Program Requirements for the Mandatory Agency-wide Quality System*, U.S. Environmental Protection Agency, Washington, DC.

Gee, G., Richardson, W., and Wortman, B. (1996). *CQM Primer*, Quality Council of Indiana, West Terra Haute, IN.

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U.S. Environmental Protection Agency, 2000. *The Data Quality Objectives Process for Hazardous Waste Sites (QA/G-4HW)*, EPA/600/R-00/007, Office of Environmental Information.

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U.S. Environmental Protection Agency, 2000. *Guidance on Technical Assessments for Environmental Data Operations (QA/G-7)*, EPA/600/R-99/080 Office of Environmental Information.

U.S. Environmental Protection Agency, 2000. *EPA Requirements for Quality Assurance Project Plans (QA/R-5) - Interim Final*, EPA/600/R-99/033, Office of Environmental Information.

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U.S. Environmental Protection Agency, 1998. *Guidance for Data Quality Assessment: Practical Methods for Data Analysis (QA/G-9)*, EPA/600/R-96/084, Office of Research and Development.

U.S. Environmental Protection Agency, 1998. *Guidance for Quality Assurance Project Plans (QA/G-5)*, EPA/600/R-98/018, Office of Research and Development.

U.S. Environmental Protection Agency, 1996. *Data Validation Functional Guidelines for Evaluating Environmental Analyses*, Region I, EPA-New England.

U.S. Environmental Protection Agency, 1995. *Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents (QA/G-6)*, EPA/600/R-96/027, Office of Research and Development.

U.S. Environmental Protection Agency, 1994. *Guidance for the Data Quality Objectives Process (QA/G-4)*, EPA/600/R-96/055, Office of Research and Development.

APPENDIX A.
QUALITY SYSTEM TOOLS

The components used to develop and implement a Quality System were discussed in Section 4.4. For each component, EPA has developed tools to assist in implementation (see Box A-1 for a summary). The sections below describe these tools and provide references to the documents that discuss the subjects in greater detail.

Box A-1. Quality Management Tools

Program/Organization Level Tools	Project Level Tools
• Quality Management Plans • Quality System Audits • QA Annual Report and Work Plan • QA Training Program	• The Data Quality Objectives Process • QA Project Plans • Standard Operating Procedures • Technical Assessments • Data Validation and Verification • Data Quality Assessment

A.1 Program/Organizational-Level Tools

A.1.1 Quality Management Plan

Purpose: To document an organization's quality system for planning, implementing, and assessing the effectiveness of activities supporting environmental programs. It also documents how, when, and by whom an organization's quality system will be implemented and assessed.

Requirement: Both EPA and non-EPA organizations are required to document their quality systems in a Quality Management Plan (or equivalent).

Background: A Quality Management Plan documents an organization's quality system for planning, implementing, and assessing the effectiveness of activities supporting environmental programs. It also documents how, when, and by whom an organization's quality system will be implemented and assessed.

References: EPA Order 5360, *The EPA Quality Manual* - Chapter 3 (EPA Only)

EPA Requirements for Quality Management Plans (QA/R-2) (EPA 2000)

Documenting Quality for ISO 9000 and Other Industry Standards (MacLean, 1993)

A.1.2 Quality System Audits

Purpose: To verify, by examination and evaluations of objective evidence, that applicable elements of the quality system are appropriate and have been developed, documented, and effectively implemented in accordance and in conjunction with specified requirements (Smith and Russell, 1997).

Requirement: EPA organizations are required to assess their quality systems on at least an annual basis.

References: *The Quality Audit Handbook*, (Smith and Russell, 1997)

A.1.3 QA Annual Report and Work Plans

Purpose: To document an EPA organization's previous year's QA and QC activities and those planned for the current year, including current and planned resources for the management and implementation of QA and QC activities, training, accomplishments, and assessments and facilitates communication between QA staff and management.

Requirement: EPA organizations are required to submit a QA Annual Report and Work Plan to the Assistant Administrator of the Office of Environmental Information every year.

References: EPA Order 5360, *The EPA Quality Manual* - Chapter 4

A.1.4 Training Program

Purpose: To assure that all personnel have the necessary skills in order to effectively accomplish their work and that quality management responsibilities and requirements are understood at every stage of project implementation throughout the Agency.

Requirement: EPA organizations are required to provide training, for all levels of management and staff, to assure that QA and QC responsibilities and requirements are understood at every stage of project implementation;

References: *Guidance for Developing a Quality Assurance Training Program (QA/G-10)* (EPA 2000)

A.2 Project-level Components

A.2.1 Systematic Planning and the Data Quality Objectives Process

Purpose: To identify the expected outcome of the project, the technical goals, the cost and schedule, and the acceptance criteria for the final result before a project begins. EPA recommends using the Data Quality Objectives Process when data are being used to select between two opposing conditions, such as determining compliance with a standard.

Requirement: EPA organizations must use a systematic planning process to develop acceptance or performance criteria for the collection, evaluation, or use of environmental data.

References: *Guidance for the Data Quality Objectives Process (QA/G-4)* (EPA 1994a)

The Data Quality Objectives Process for Hazardous Waste Sites (QA/G-4HW) (EPA 2000).

A.2.2 Quality Assurance Project Plans

Purpose: To document performance criteria and the project-specific plan for obtaining the type, quality, and quantity of data needed for a specific use.

Requirement: An EPA-approved QA Project Plan (or equivalent) is required for all projects and tasks involving environmental data collection.

References: EPA Order 5360, *The EPA Quality Manual* - Chapter 5 (EPA Only)

EPA Requirements for Quality Assurance Project Plans (QA/R-5) (EPA 2000)

Guidance for Quality Assurance Project Plans (QA/G-5) (EPA 1998b)

A.2.3 Standard Operating Procedures

Purpose: To document the procedures necessary to carry out routine or repetitive administrative and technical activities.

Requirement: Not Applicable.

References: *Guidance for the Preparation of Standard Operating Procedures for Quality-Related Documents (QA/G-6)* (EPA 1995)

A.2.4 Technical Assessments

Purpose: To provide a systematic independent technical examination of a project to determine if a data collection activity is being conducted as planned and producing data and information of the type and quality specified in the QA Project Plan.

Requirement: Not Applicable.

References: *Guidance on Technical Audits and Related Assessments for Environmental Data Operations (QA/G-7)* (EPA 2000).

A.2.5 Data Verification and Validation

Purpose: To determine if data has been collected in accordance to the QA Project Plan with respect to compliance, correctness, consistency, and completeness and to evaluate the technical usability of the data with respect to the planned objectives or intention of the project.

Requirement: Not Applicable.

References: *Data Validation Functional Guidelines for Evaluating Environmental Analyses* (EPA 1996).

A.2.6 Data Quality Assessment

Purpose: To provide a scientific and statistical assessment to determine whether data are of the right type, quality, and quantity to support a specific use.

Requirement: Not Applicable.

References: *Guidance for Data Quality Assessment: Practical Methods for Data Analysis (QA/G-9)* (EPA 1998)

Bibliography of References for Assessing Secondary Data (EPA 2000) (available at www.epa.gov/quality)